

5.0 510(k) Summary**5.1 Preparation Date: 05-13-2011****Submitted By**

David Binks MT (ASCP), MBA
Director of QA/Regulatory Affairs
Arlington Scientific, Inc.
1840 North Technology Dr.
Springville, UT 84663
Phone 801-489-8911 / Fax 801-489-5552

5.2 Trade Name – ASiManager-AT

Common Name – Densitometer/scanner

Classification Name (21 CFR 862.2400) Densitometer/scanner (integrating, reflectance, TLC, or radiochromatogram) for clinical use.

5.3 Predicate Device(s) – ASI RPR Card Test for Syphilis – K851504

5.4 Device Description – The ASiManager-AT is an integrated digital particle analyzer designed to objectively interpret certain slide agglutination tests manufactured by Arlington Scientific Inc. (ASI). Qualitative and semiquantitative tests are performed by laboratory professionals who use the ASiManager-AT to provide standardized test interpretation using criteria that define reactive and nonreactive agglutination reactions. The ASiManager-AT also delivers an initial predictive titer analysis for the ASI RPR Card Test for Syphilis.

The ASiManager-AT employs a CCD (charge-coupled device) camera that uses light reflectance to create a highly sensitive and high-resolution image of the agglutination immunoassay. This image is then analyzed by the proprietary software algorithm to interpret the agglutination pattern.

The ASiManager-AT further provides tools that enable the creation, storage, retrieval and transmittal of the test results.

Intended Use – The ASiManager-AT is intended to be used as an integrated digital particle analyzer to objectively interpret the ASI RPR Card Test for Syphilis. The ASiManager-AT is designed to provide standardized test interpretation, an initial predictive titer analysis, and provides for storage, retrieval, and transmittal of the test results. It is intended to be acquired, possessed and used only by health care professionals. For *in vitro* Diagnostic Use Only, not intended for screening blood and tissue donors.

5.5 Summary of Comparison Data – A comparison of the digital interpretation of the results of testing samples with the ASI RPR Card Test for Syphilis using the **ASiManager-AT** and visual interpretation by trained laboratory professionals was conducted to show substantial equivalence.

The following data are the results from three testing sites:

Combined Prospective Sample Testing - 375 Samples

ASiManager-AT Digital Results			
Visual Results		Reactive	Nonreactive
	Reactive	3	0
	Nonreactive	0	372

These results give a percent agreement positive of 100% with reactive samples and 100% with nonreactive samples.

Combined Retrospective Sample Testing - 3131 Samples

ASiManager-AT Digital Results			
Visual Results		Reactive	Nonreactive
	Reactive	1799	58
	Nonreactive	29	1245

These results give a percent agreement positive of 98.4% with reactive samples and 95.5% with nonreactive samples.

Of the 1849 reactive samples from the qualitative testing 1224 were used to determine the predictive titer. The **ASiManager-AT** is programmed to project or predict the endpoint titer of each qualitative test by reading the undiluted serum (1:1) and determining its corresponding endpoint for reactive serums. This is done using a proprietary algorithm that interprets the reaction in the undiluted sample and projects what the endpoint titer of the sample will be. A one dilution difference is an acceptable range for equivalency because the minimal reactive endpoint titer is subject to interpretation between different observers due to many factors such as lighting, visual acuity, and fatigue, etc. Of the 1224 reactive samples tested 1146 were within the ± 1 titer acceptance criteria, for a concordance of 93.6%

Of the 1849 reactive samples from the qualitative testing 708 were used to determine the endpoint titer. The **ASiManager-AT** is programmed to determine the true endpoint titer of a serial diluted specimen using the RPR endpoint titer function on the instrument. The RPR endpoint titer (semiquantitative) function analyzes the entire card and identifies in which well the serial diluted sample becomes nonreactive. The software then calculates the endpoint titer. A one dilution difference is an acceptable range for equivalency because the minimal reactive endpoint titer is subject to interpretation between different observers due to many factors such as lighting, visual acuity, and fatigue, etc. Of the 708 reactive samples tested 700 were within the ± 1 titer acceptance criteria, for a concordance of 98.9%

5.6 Conclusion – The ASiManager-AT is safe and effective for its intended use.



Arlington Scientific, Inc.
c/o Mr. David Binks
Director of QA/Regulatory Affairs
1840 North Technology Drive
Springville, UT 84663

NOV - 9 2011

Re: k111356
Trade/Device Name: ASiManager-AT
Regulation Number: 21CFR §862.2400
Regulation Name: Densitometer/scanner (intergrating,reflectance, TLC, or
radiochromatogram) for clinical use
Regulatory Class: Class I
Product Code: JQT
Dated: November 7, 2011
Received: November 8, 2011

Dear Mr. Binks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

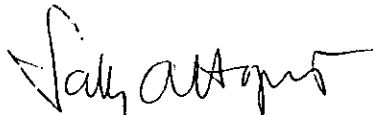
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a

legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Sally A. Hojvat', with a stylized flourish at the end.

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):

Device Name: **ASiManager-AT**

Indications for Use:

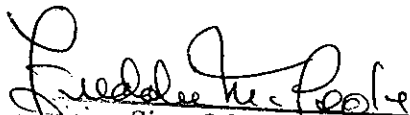
The ASiManager-AT is intended to be used as an integrated digital particle analyzer to objectively interpret the ASI RPR Card Test for Syphilis. The ASiManager-AT is designed to provide standardized test interpretation, an initial predictive titer analysis, and provides for storage, retrieval, and transmittal of the test results. It is intended to be acquired, possessed and used only by health care professionals. For *in vitro* Diagnostic Use Only, not intended for screening blood and tissue donors.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)


Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K 111 356